DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 9, 2015

MICROGENICS CORPORATION
LAURIE WONG
MANAGER, REGULATORY AFFAIRS
46500 KATO ROAD
FREMONT CA 94538

Re: K150502
Trade/Device Name: DRI Hydrocodone Assay,
DRI Hydrocodone Calibrators,
DRI Hydrocodone Controls
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate Test System
Regulatory Class: II
Product Code: DJG, DLJ, LAS
Dated: August 14, 2015
Received: August 19, 2015

Dear Ms. Wong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the

electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150502

Device Name
DRI® Hydrocodone Assay
DRI® Hydrocodone Calibrators
DRI® Hydrocodone Controls

Indications for Use *(Describe)*

DRI® Hydrocodone Assay

The DRI® Hydrocodone Assay is intended for the qualitative and semi-quantitative detection and estimation of Hydrocodone and its metabolites in human urine at a cutoff of 300 ng/mL. The semi-quantitative mode is for purposes of enabling laboratories to determine an appropriate dilution of specimen for confirmation by a confirmatory method such as LC-MS/MS or GC-MS and permitting laboratories to establish quality control measures.

This assay provides a preliminary analytical test result. A more specific alternative chemical method must be used in order to confirm an analytical result. Gas chromatography/mass spectrometry (GC/MS) and Liquid Chromatography/ tandem mass spectrometry (LC-MS/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

DRI® Hydrocodone Calibrators

The DRI® Hydrocodone Assay Calibrators are intended for the calibration of the DRI® Hydrocodone Assay. For In Vitro Diagnostic Use Only.

DRI® Hydrocodone Controls

The DRI® Hydrocodone Controls are unassayed quality control material intended for use in the DRI Hydrocodone Assay to detect and monitor systematic deviations from accuracy resulting from reagent or instrument defects. For In Vitro Diagnostics Use Only

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient details to understand the basis for a determination of substantial equivalence.

Submitter Name, Address and Content:

Microgenics
46500 Kato Road
Fremont, CA 94538
Phone: (510) 979-5000
Fax: (510) 979-5002
Email: laurie.wong@thermofisher.com

Contact: Laurie Wong
Regulatory Affairs Manager

Date Summary Originally Prepared: February 25, 2015
Date Summary updated per FDA request of October 1, 2015

Device Name and Classification

Trade or Proprietary Name:

DRI® Hydrocodone Assay
DRI® Hydrocodone Assay Calibrators
DRI® Hydrocodone Assay Controls

Common Name: Homogeneous Hydrocodone Enzyme Immunoassay

Classification Name:

Enzyme Immunoassay, Hydrocodone
Class II, DJG (91 Toxicology)
21 CFR 862.3650

Drug Specific Calibrators
Class II, DLJ (91 Toxicology)
21 CFR 862.3200

Drug Specific Controls
Class I, Reserved LAS (91 Toxicology)
21 CFR 862.3280

Legally Marketed Predicate Device(s)

The DRI® Hydrocodone Assay is substantially equivalent to the predicate Lin-Zhi International, Inc., LZI Hydrocodone Enzyme Immunoassay (K141055). The DRI® Hydrocodone Assay, calibrators, and controls are identical or similar to the predicate in terms of intended use, method principle, device components, and clinical performance.

Device Description

The DRI® Hydrocodone Assay is supplied as a liquid ready-to-use homogeneous enzyme immunoassay. The assay uses specific antibodies that can detect Hydrocodone and its metabolites without any significant cross-reactivity to other opiate compounds. The assay is based on competition between a drug labeled with glucose-6-phosphate dehydrogenase (G6PDH) and free drug from the urine sample, for a fixed amount of specific antibody binding sites. In the absence of free drug from the sample, the specific antibody binds the drug labeled with G6PDH and causes a decrease in enzyme activity. In the presence of free drug, the free drug occupies the antibody binding sites, allowing the drug bound G6PDH to interact with the substrate, resulting in enzyme activity. This phenomenon creates a direct relationship between the drug concentration in urine and enzyme activity. The enzyme activity is determined spectrophotometrically at 340 nm by measuring the conversion of nicotinamide adenine dinucleotide (NAD) to NADH.

The DRI® Hydrocodone Assay is a kit comprised of two reagents, Reagent A and Reagent E, which are bottled separately but sold together within the same kit.

The Reagent A solution contains: mouse monoclonal anti-hydrocodone antibody, glucose-6-phosphate (G6P) and nicotinamide adenine dinucleotide (NAD) in Tris buffer with Sodium Azide (≤0.09%) as a preservative). The Reagent E solution contains: glucose-6-phosphate dehydrogenase (G6PDH) in Tris buffer with Sodium Azide (≤0.09%) as preservative.

The DRI® Hydrocodone Enzyme Immunoassay calibrators designated for use at the 300 ng/mL cutoff contain 0 (negative), 100, 300, 500, and 1,000 ng/mL of hydrocodone in human urine matrix with sodium azide (≤0.09%) as preservative. The controls are provided at a concentration

of 225 and 375 ng/mL. The calibrators are sold separately and the two controls are sold as a kit.

Intended Use

The DRI® Hydrocodone Assay is intended for the qualitative and semi-quantitative detection and estimation of Hydrocodone and its metabolites in human urine at a cutoff of 300 ng/mL. The semi-quantitative mode is for purposes of enabling laboratories to determine an appropriate dilution of specimen for confirmation by a confirmatory method such as LC-MS/MS or GC-MS and permitting laboratories to establish quality control measures.

This assay provides a preliminary analytical test result. A more specific alternative chemical method must be used in order to confirm an analytical result. Gas chromatography/mass spectrometry (GC/MS) and Liquid Chromatography/tandem mass spectrometry (LC-MS/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

The DRI® Hydrocodone Assay Calibrators are intended for the calibration of the DRI® Hydrocodone Assay. For In Vitro Diagnostic Use Only.

The DRI® Hydrocodone Controls are unassayed quality control material intended for use in the DRI Hydrocodone Assay to detect and monitor systematic deviations from accuracy resulting from reagent or instrument defects. For In Vitro Diagnostics Use Only

Comparison to Predicate Device

The DRI® Hydrocodone Assay is substantially equivalent to the predicate Lin-Zhi International, Inc., LZI Hydrocodone Enzyme Immunoassay, Calibrators and Controls cleared by the FDA under the premarket notification K141055 for its stated intended use.

The following table (next page) compares the DRI® Hydrocodone Assay to the predicate device.

Device **Characteristics**	**Subject Device** **DRI Hydrocodone Assay, Calibrators, and Controls**	**Predicate Device** **LZI Hydrocodone Enzyme Immunoassay, Calibrators and Controls (K141055)**
Intended Use	The DRI® Hydrocodone Assay is intended for the qualitative and semi-quantitative detection and estimation of Hydrocodone and its metabolites in human urine at a cutoff of 300 ng/mL. The semi-quantitative mode is for purposes of enabling laboratories to determine an appropriate dilution of specimen for confirmation by a confirmatory method such as LC-MS/MS or GC-MS and permitting laboratories to establish quality control measures. This assay provides a preliminary analytical test result. A more specific alternative chemical method must be used in order to confirm an analytical result. Gas chromatography/mass spectrometry (GC/MS) and Liquid Chromatography/tandem mass spectrometry (LC-MS/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used. The DRI® Hydrocodone Assay Calibrators are intended for the calibration of the DRI® Hydrocodone Assay. The DRI® Hydrocodone Controls are used to validate the DRI® Hydrocodone Assay calibration. For In Vitro Diagnostics Use Only.	The LZI Hydrocodone Enzyme Immunoassay, when used in conjunction with the AU480 automated clinical system analyzers, is intended for the qualitative and semi-quantitative determination of hydrocodone in human urine at cutoff values of 100 or 300 ng/mL. The assay is designed for professional use with a number of automated clinical chemistry analyzers. This assay provides a rapid screening procedure for determining the presence of hydrocodone and hydromorphone in urine. The assay provides only a preliminary analytical result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result Gas or liquid chromatography/mass spectrometry (GC/MS or LC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary test result is positive.
Analyte	Hydrocodone	Hydrocodone

Cutoff Level	300 ng/mL	100 or 300 ng/mL
Sample Matrix	Human Urine Matrix	Human Urine Matrix
Calibrators Level	300 ng/mL Cutoff: 5 levels: 0, 100, 300, 500 and 1,000 ng/mL	100 ng/mL Cutoff: 5 levels: 0, 50, 100, 150, and 300 ng/mL 300 ng/mL Cutoff: 5 levels: 0, 150, 300, 500, and 800 ng/mL
Controls Level	300 ng/mL Cutoff: 2 Levels (225 ng/mL and 375 ng/mL)	100 ng/mL Cutoff: 2 Levels (75 ng/mL, 125 ng/mL)
Test Principle	The DRI® Hydrocodone Assay is supplied as a liquid ready-to-use homogeneous enzyme immunoassay. The assay uses specific antibodies that can detect Hydrocodone without any significant cross-reactivity to other opiate compounds. The assay is based on competition between a drug labeled with glucose-6-phosphate dehydrogenase (G6PDH) and free drug from the urine sample, for a fixed amount of specific antibody binding sites. In the absence of free drug from the sample, the specific antibody binds the drug labeled with G6PDH and causes a decrease in enzyme activity. This phenomenon creates a direct relationship between the drug concentration in urine and enzyme activity. The enzyme activity is determined spectrophotometrically at 340 nm by measuring the conversion of nicotinamide adenine dinucleotide (NAD) to NADH.	The LZI Hydrocodone Enzyme Immunoassay is a liquid ready-to-use homogeneous enzyme immunoassay. The assay uses specific antibodies that can detect Hydrocodone without any significant cross-reactivity to other opiate compounds.
Storage	2-8°C until expiration date	2-8°C until expiration date

Performance Characteristics Summary:

AU680 Analyzer

Precision: 300 ng/mL Cutoff

Samples spiked with various amounts of Hydrocodone were tested in both qualitative and semi-quantitative mode using a Clinical Laboratory and Standards Institute (CLSI) protocol. Results presented below were generated by testing all samples in replicates of two, twice per day for 20 days, total n=80.

Qualitative Results using CLSI:

			Within Run Precision (n=80)		**Total Run Precision (n=80)**	
Hydrocodone Spike Concentration (ng/mL)	**% of Cutoff**	**LC-MS/MS (ng/mL)**	**Number of determinants**	**Immunoassay Results**	**Number of determinants**	**Immunoassay Results**
0	-100%	0	80	80 Neg	80	80 Neg
75	-75%	87	80	80 Neg	80	80 Neg
150	-50%	171	80	80 Neg	80	80 Neg
225	-25%	255	80	80 Neg	80	80 Neg
300	100%	345	80	46 Neg/34 Pos	80	46 Neg/34 Pos
375	+25%	442	80	80 Pos	80	80 Pos
450	+50%	535	80	80 Pos	80	80 Pos
525	+75%	561	80	80 Pos	80	80 Pos
600	+100%	664	80	80 Pos	80	80 Pos

All samples tested recovered accurately. Samples at levels below the cutoff read as negative and samples at levels above the cutoff read as positive.

Semi-Quantitative Results Using CLSI:

			Within Run Precision (n=80)		**Total Run Precision (n=80)**	
Hydrocodone Spike Concentration (ng/mL)	**% of Cutoff**	**LC-MS/MS (ng/mL)**	**Number of determinants**	**Immunoassay Results**	**Number of determinants**	**Immunoassay Results**

0	-100%	0	80	80 Neg	80	80 Neg
75	-75%	87	80	80 Neg	80	80 Neg
150	-50%	171	80	80 Neg	80	80 Neg
225	-25%	255	80	80 Neg	80	80 Neg
300	100%	345	80	40 Neg/40 Pos	80	40 Neg/40 Pos
375	+25%	442	80	80 Pos	80	80 Pos
450	+50%	535	80	80 Pos	80	80 Pos
525	+75%	561	80	80 Pos	80	80 Pos
600	+100%	664	80	80 Pos	80	80 Pos

Accuracy

One hundred patient samples were analyzed by the DRI® Hydrocodone Assay in both qualitative and semi-quantitative modes and the results were compared to the LC-MS/MS. The overall concordance between LC-MS/MS and the DRI Hydrocodone Assay was 93%.

Qualitative Results with LC-MS/MS as reference method

DRI Hydroco-done Assay	Negative	Less than 50% of cutoff concentration by LC/MS analysis (<150 ng/mL)	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration) (150- 299 ng/mL)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration) (300-450 ng/mL)	High Positive (greater than 50% above the cutoff concentration) >450 ng/mL
Positive	0	1*	5**	10	39
Negative	31	6	7	1	0

*and ** 1 Sample in each bin has oxycodone concentrations greater than >37,000 ng/mL

Semi-Quantitative Results with LC-MS/MS as reference method

DRI Hydroco-done Assay	Negative	Less than 50% of cutoff concentration by Predicate analysis (<150ng/mL)	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration) 150- 299 ng/mL	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration) 300-450 ng/mL	High Positive (greater than 50% above the cutoff concentration) >450 ng/mL
Positive	0	1*	5**	10	39
Negative	31	6	7	1	0

*and ** 1 Sample in each bin has oxycodone concentrations greater than >37,000 ng/mL

Discordant Result Table for the Discrepant Samples near cutoff

Sample #	Qualitative EIA	LC-MS/MS (ng/mL)				Semi-Quantitative EIA (ng/mL)
		Hydrocodone	Hydromorphone	Hydormorphone 3β-D glucuronide	Adjusted Total#	
33	Positive	143.3	<LLOQ♦	67.6	210.9	369
70*	Positive	138.4	<LLOQ	<LLOQ	138	1280
75**	Positive	216.7	<LLOQ	<LLOQ	217	974
76	Positive	198.8	<LLOQ	42.6	241	319
83	Positive	78.4	<LLOQ	110.1	188.5	392

89	Positive	192.3	<LLOQ	56.2	248.5	406
96	Negative	303.3	<LLOQ	50.1	353.4	286

[#] adjusted total LC-MS/MS (ng/mL) Hydrocodone + Hydromorphone + Hydromorphone 3β-D glucuronide.

* and **Oxycodone positive samples >37,000 ng/mL.

♦LLOQ = Lowest Limit of Quantitation is 40 ng/mL

Analytical Recovery and Linearity

To demonstrate linearity for the purpose of sample dilution and quality control over the entire assay range, a drug free urine pool was spiked with Hydrocodone across the range of the calibration curve. Each sample was run in replicates of five on the AU680 instrument in semi-quantitative mode and the average was used to determine percent recovery compared to the expected target value. When comparing the result (y) and target (x) value, using the least squares regression technique, the regression equation and correlation are as follows y=1.0341-1.9933 and r2 value was 0.9965.

Linearity Results for Lot 3

Target Hydrocodone (ng/mL)	**Observed Recovery (ng/mL)** **N=5**	**Recovery %**
0	N/A	N/A
50	47	94
75	76	101
100	108	108
150	171	114
225	250	111
300	302	101
375	398	106
450	472	105
500	527	105
750	844	113
1000	1014	101

The results demonstrated that the data passed the acceptance criteria. The LC-MS/MS data demonstrated the values were within the acceptance criteria. The results indicated that the

dilution linearity exists across the calibrator range.

Specificity and Cross-Reactivity

Several opiates (structurally similar or dissimilar to Hydrocodone) were tested for cross-reactivity in the DRI® Hydrocodone Assay. Cross-reactant solutions were prepared by adding known amounts of stock solution to the drug free urine.

Hydrocodone, and its metabolites listed in the table were titrated to the lowest levels yielding a positive result in the assay.

Structurally related and unrelated opiates listed in the table were tested and results are shown below.

Cross-Reactivity Results for Lot 3

Hydrocodone and its metabolites	**Tested Concentration (ng/mL)**	**Pos/Neg**	**% Cross-reactivity**
Neg urine	0	Pos	0%
Hydrocodone	300	Pos	102%
Hydromorphone	250	Pos	122%
Hydromorphone-3β-glucuronide	250	Pos	122%
Norhydrocodone	10,000	Pos	3.1%
Dihydrocodeine	11,000	Pos	2.7%

Structurally related compounds and other opiates	**Tested Concentration (ng/mL)**	**Pos/Neg**	**% Cross-reactivity**
6-Acetyl Morphine	100,000	Neg	< 0.3%
Buprenorphine	100,000	Neg	< 0.3%
Buprenorphine-3β-D-glucuronide	100,000	Neg	< 0.3%
Codeine	150,000	Neg	< 0.2%
Dextromethorphan	250,000	Neg	< 0.2%
EDDP	150,000	Neg	< 0.2%
Fentanyl	100,000	Neg	< 0.3%
Heroin	100,000	Neg	< 0.3%
Levorphanol	18,000	Pos	1.7%

Structurally related compounds and other opiates	Tested Concentration (ng/mL)	Pos/Neg	% Cross-reactivity
Methadone	100,000	Neg	< 0.3%
Meperidine	100,000	Neg	< 0.3%
Morphine	150,000	Neg	< 0.2%
Morphine-3β-D-glucuronide	70,000	Neg	< 0.4%
Morphine-6β-D-glucuronide	75,000	Neg	< 0.4%
Nalbuphine	150,000	Neg	< 0.3%
Naloxone	15,000	Pos	2.0%
Naltrexone	100,000	Neg	< 0.3%
Norbuprenorphine	100,000	Neg	< 0.3%
Norcodeine	150,000	Neg	< 0.2%
Normorphine	150,000	Neg	< 0.2%
NorOxycodone	100,000	Pos	0.3%
Oxycodone	12,000	Pos	2.5%
Oxymorphone-6β-D-glucuronide	14,000	Pos	2.2%
Oxymorphone	12,000	Pos	2.5%
Tapentadol	100,000	Neg	< 0.3%
Thebaine	100,000	Neg	< 0.3%
Tramadol	100,000	Neg	< 0.3%

Interference

The potential interference of pH and endogenous physiologic substances on recovery of Hydrocodone using DRI® Hydrocodone Assay was assessed by spiking known compounds of potentially interfering substances into the low (225 ng/mL) and high (375 ng/mL) controls for 300 ng/mL cutoff. In the presence of the compounds listed below, the controls were detected accurately indicating that these compounds did not show interference in the assay. The samples were tested in both qualitative and semi-quantitative mode.

		Summary of Results		
Cross Reactants	**Spiked Concentration (ng/mL)**	**Negative urine SQ**	**Low Control QUAL**	**High Control QUAL**
Neg urine	0	Neg	Neg	Pos

		Summary of Results		
Cross Reactants	**Spiked Concentration (ng/mL)**	**Negative urine SQ**	**Low Control QUAL**	**High Control QUAL**
Acetaminophen	10	Neg	Neg	Pos
Acetone	500	Neg	Neg	Pos
Acetyl Salycylic Acid	10	Neg	Neg	Pos
Ascorbic Acid	150	Neg	Neg	Pos
Caffeine	10	Neg	Neg	Pos
Creatinine	400	Neg	Neg	Pos
Ethanol	10	Neg	Neg	Pos
Galactose	5	Neg	Neg	Pos
Glucose	1000	Neg	Neg	Pos
Hemoglobin	150	Neg	Neg	Pos
Human Serum Albumin	200	Neg	Neg	Pos
Ibuprophen	10	Neg	Neg	Pos
Oxalic acid	50	Neg	Neg	Pos
Riboflavin	3	Neg	Neg	Pos
Sodium Chloride	1000	Neg	Neg	Pos
Urea	1000	Neg	Neg	Pos
pH	4	Neg	Neg	Pos
pH	5	Neg	Neg	Pos
pH	6	Neg	Neg	Pos
pH	7	Neg	Neg	Pos

		Summary of Results		
Cross Reactants	**Spiked Concentration (ng/mL)**	**Negative urine SQ**	**Low Control QUAL**	**High Control QUAL**
pH	8	Neg	Neg	Pos
pH	9	Neg	Neg	Pos
pH	10	Neg	Neg	Pos

Specific Gravity

Drug Free urine samples with specific gravity ranging in value from 1.000 to 1.036 g/mL were split and either left unspiked or spiked to a final concentration of either 225 ng/mL or 375 ng/mL (the low and high control concentrations, respectively). These samples were then evaluated in qualitative and semi-quantitative modes. No interference was observed.

Spiked Hydrocodone Concentration		
Specific Gravity (g/mL)	**Low Control 225 ng/mL**	**High Control 375 ng/mL**
1.000	Neg	Pos
1.006	Neg	Pos
1.007	Neg	Pos
1.010	Neg	Pos
1.013	Neg	Pos
1.018	Neg	Pos
1.021	Neg	Pos
1.025	Neg	Pos
1.028	Neg	Pos

1.034	Neg	Pos
1.036	Neg	Pos

Stability:

Open Vial Calibrators and Controls

Open vial stability studies for three lots stored at 2-8°C were carried out to support a claim of 60 days at this time for qualitative and semi-quantitative.

Real Time Stability for Reagent, Calibrators and Controls

Real time studies for reagents, calibrators and controls at 2-8°C are ongoing and have been carried out up to 289 days.

Accelerated Stability Results for Reagents, Calibrators and Controls

Accelerated testing results show that the low control was detected as negative and the high control was detected as positive for each time point for a period of 4 months at 23°C. This is equivalent to 13 months of stability according to Q10 math model. The % recoveries of the low and high control were within 80-120%. The data for six month accelerated stability also confirmed that the low control was detected as negative and the high control was detected as positive.

Summary

As summarized, the DRI® Hydrocodone Assay is substantially equivalent to the legally marketed predicate LZI Hydrocodone Enzyme Immunoassay (Lin Zhi International) for the declared intended use. Substantial equivalence has been demonstrated through a comparison of the intended use and device characteristics when comparing the subject device to the legally marketed predicate. Performance testing was completed to verify that the device functions as intended and that design specifications have been satisfied. The content of the pre-market notification for the DRI® Hydrocodone Assay provides evidence that the device is safe and effective for the intended use.